PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

To: ALEXANDER SMOLENSKI
SUNSTEIN KANN MURPHY & TIMBERS LLP
125 SUMMER STREET
BOSTON, MA 02110

PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL SEARCH REPORT AND THE WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

	Date of mailing *(day/month/year)*
Applicant's or agent's file reference 2960/189WO	**FOR FURTHER ACTION** See paragraphs 1 and 4 below
International application No. PCT/US2010/025459	International filing date *(day/month/year)* 25 February 2010
Applicant CONFORMIS, INC.	

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

   Filing of amendments and statement under Article 19:
   The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):

   When? The time limit for filing such amendments is normally two months from the date of transmittal of the international search report.

   Where? Directly to the International Bureau of WIPO, 34 chemin des Colombettes 1211 Geneva 20, Switzerland, Facsimile No.: +41 22 338 82 70

   For more detailed instructions, see the notes on the accompanying sheet.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.

3. ☐ **With regard to the protest** against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

   ☐ the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.

   ☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Reminders**

   Shortly after the expiration of **18 months** from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90*bis*.1 and 90*bis*.3, respectively, before the completion of the technical preparations for international publication.

   The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established. These comments would also be made available to the public but not before the expiration of 30 months from the priority date.

   Within **19 months** from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase **until 30 months** from the priority date (in some Offices even later); otherwise, the applicant must, **within 20 months** from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.

   In respect of other designated Offices, the time limit of **30 months** (or later) will apply even if no demand is filed within 19 months.

   See the Annex to Form PCT/IB/301 and, for details about the applicable time limits, Office by Office, see the *PCT Applicant's Guide*, Volume II, National Chapters and the WIPO Internet site.

Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: Blaine R. Copenheaver Telephone No. 571-272-7774

Form PCT/ISA/220 (January 2004) *(See notes on accompanying sheet)*

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

To: ALEXANDER SMOLENSKI
SUNSTEIN KANN MURPHY & TIMBERS LLP
125 SUMMER STREET
BOSTON, MA 02110

PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL SEARCH REPORT AND THE WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

Applicant's or agent's file reference 2960/189WO	Date of mailing *(day/month/year)* 20 APR 2010 **FOR FURTHER ACTION** See paragraphs 1 and 4 below
International application No. PCT/US2010/025459	International filing date *(day/month/year)* 25 February 2010
Applicant CONFORMIS, INC.	

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   Filing of amendments and statement under Article 19:
   The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):

   When? The time limit for filing such amendments is normally two months from the date of transmittal of the international search report.

   Where? Directly to the International Bureau of WIPO, 34 chemin des Colombettes 1211 Geneva 20, Switzerland, Facsimile No.: +41 22 338 82 70

   For more detailed instructions, see the notes on the accompanying sheet.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.

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   ☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

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   Within **19 months** from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase **until 30 months** from the priority date (in some Offices even later); otherwise, the applicant must, **within 20 months** from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.

   In respect of other designated Offices, the time limit of **30 months** (or later) will apply even if no demand is filed within 19 months.

   See the Annex to Form PCT/IB/301 and, for details about the applicable time limits, Office by Office, see the *PCT Applicant's Guide*, Volume II, National Chapters and the WIPO Internet site.

Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: Blaine R. Copenheaver Telephone No. 571-272-7774

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To: ALEXANDER SMOLENSKI
SUNSTEIN KANN MURPHY & TIMBERS LLP
125 SUMMER STREET
BOSTON, MA 02110

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

	Date of mailing *(day/month/year)*
Applicant's or agent's file reference 2960/189WO	**FOR FURTHER ACTION** See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US2010/025459	25 February 2010	24 June 2009

International Patent Classification (IPC) or both national classification and IPC
IPC(8) - A61F 2/30 (2010.01)
USPC - 623/18.11

Applicant CONFORMIS, INC.

1. This opinion contains indications relating to the following items:

- [X] Box No. I Basis of the opinion
- [ ] Box No. II Priority
- [X] Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- [ ] Box No. IV Lack of unity of invention
- [X] Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- [ ] Box No. VI Certain documents cited
- [ ] Box No. VII Certain defects in the international application
- [ ] Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/US	Date of completion of this opinion	Authorized officer:
Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	09 April 2010	Blaine R. Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 2960/189WO	**FOR FURTHER ACTION**	see Form PCT/ISA/220 as well as, where applicable, item 5 below.
International application No. PCT/US2010/025459	International filing date *(day/month/year)* 25 February 2010	(Earliest) Priority Date *(day/month/year)* 24 June 2009
Applicant CONFORMIS, INC.		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 3 sheets.

☐ It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**

   a. With regard to the **language**, the international search was carried out on the basis of:

   ☒ the international application in the language in which it was filed.

   ☐ a translation of the international application into _____ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

   b. ☐ This international search report has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43.6*bis*(a)).

   c. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. ☒ **Certain claims were found unsearchable** (see Box No. II).

3. ☐ **Unity of invention is lacking** (see Box No. III).

4. With regard to the **title**,

   ☒ the text is approved as submitted by the applicant.

   ☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

   ☒ the text is approved as submitted by the applicant.

   ☐ the text has been established, according to Rule 38.2, by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. With regard to the **drawings**,

   a. the figure of the **drawings** to be published with the abstract is Figure No. 3A

   ☒ as suggested by the applicant.

   ☐ as selected by this Authority, because the applicant failed to suggest a figure.

   ☐ as selected by this Authority, because this figure better characterizes the invention.

   b. ☐ none of the figures is to be published with the abstract.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2010/025459

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☒ Claims Nos.: 16
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2010/025459

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61F 2/30 (2010.01)
USPC - 623/18.11
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC(8) - A61B 17/56; A61F 2/30, 2/36, 2/38, 2/46 (2010.01)
USPC - 606/79, 88; 623/11.11, 16.11, 18.11, 20.14, 20.21, 20.31, 20.35

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
PatBase

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2006/058057 A2 (BURDULIS et al) 01 June 2006 (01.06.2006) entire document	1-15, 17-23
Y		24-35
X	US 2008/0009950 A1 (RICHARDSON) 10 January 2008 (10.01.2008) entire document	36-40
Y		24-35, 41-43
Y	WO 03/051210 A2 (EK et al) 26 June 2003 (26.06.2003) entire document	41-43

☐ Further documents are listed in the continuation of Box C. ☐

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
09 April 2010	20 APR 2010
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: Blaine R. Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/210 (second sheet) (July 2009)

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To: ALEXANDER SMOLENSKI
SUNSTEIN KANN MURPHY & TIMBERS LLP
125 SUMMER STREET
BOSTON, MA 02110

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing *(day/month/year)*	20 APR 2010
Applicant's or agent's file reference 2960/189WO	**FOR FURTHER ACTION** See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US2010/025459	25 February 2010	24 June 2009

International Patent Classification (IPC) or both national classification and IPC
IPC(8) - A61F 2/30 (2010.01)
USPC - 623/18.11

Applicant CONFORMIS, INC.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/US	Date of completion of this opinion	Authorized officer:
Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	09 April 2010	Blaine R. Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2010/025459

Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of:

   ☒ the international application in the language in which it was filed.

   ☐ a translation of the international application into _____ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43*bis*.1(a))

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of a sequence listing filed or furnished:

   a. (means)

      ☐ on paper

      ☐ in electronic form

   b. (time)

      ☐ in the international application as filed

      ☐ together with the international application in electronic form

      ☐ subsequently to this Authority for the purposes of search

4. ☐ In addition, in the case that more than one version or copy of a sequence listing has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

5. Additional comments:

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2010/025459

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application.

☒ claims Nos. 16

because:

☐ the said international application, or the said claims Nos. _____ relate to the following subject matter which does not require an international search *(specify)*:

☒ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. 16 are so unclear that no meaningful opinion could be formed *(specify)*:

Claim 16 is a multiple dependent claim not drafted in accordance with the second and third sentences of Rule 6.4(a).

☐ the claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed *(specify)*:

☒ no international search report has been established for said claims Nos. 16

☐ a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:

- ☐ furnish a sequence listing on paper complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.
- ☐ furnish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.
- ☐ pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rule 13*ter*.1(a) or (b).

☐ See Supplemental Box for further details.

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2010/025459

Box No. V **Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims	4, 8, 23-35, 37, 41-43	YES
	Claims	1-3, 5-7, 9-15, 17-22, 36, 38-40	NO
Inventive step (IS)	Claims	None	YES
	Claims	1-15, 17-43	NO
Industrial applicability (IA)	Claims	1-15, 17-43	YES
	Claims	None	NO

2. Citations and explanations:

Claims 1-3, 5-7, 9-15, and 17-22 lack novelty under PCT Article 33(2) as being anticipated by Burdulis et al. (hereinafter Burdulis).

Regarding claim 1, Burdulis discloses a pre-primary articular implant component (Title and Abstract) comprising: (a) an outer, joint-facing surface (curved mating surface 302) comprising a bearing surface portion (para. 0127 describes a weight bearing surface of Fig. 3-8, such as the outer surface shown in Fig. 3H-3I; para. 0152-0155 describes using the implant to replace an articular weight bearing surface); and (b) an inner, bone-facing surface (named convex joint abutting surface or bone mating surface 304; para. 0089-0091 describes how surface 304 faces the bone, shown in Fig. 3G, and held in place via anchors 306; para. 0091) comprising one or more patient-engineered bone cuts selected and/or designed from patient-specific data (para. 0089 describes designing the surface of the implant to abut the bone, where para. 0095 & Fig. 3J-3K show examples of the cuts made to match the implant with the portion of the patient's bone where the device will be used; para. 0096 & Fig. 4A show an additional embodiment where a series of cuts are made on the device; para. 0170 describes designing the implant to be made to order for an individual patient, where the fit is based upon patient information; Fig. 1A-1C show a procedure for obtaining patient data).

Regarding claims 2, 3, 5-7, and 9, Burdulis discloses the pre-primary articular implant component of claim 1, and Burdulis further discloses [claim 2] wherein the one or more patient-engineered bone cuts (para. 0096 & Fig. 4A show an additional embodiment that describes the bone cuts, which can be performed on the implant 300) are selected and/or designed from patient-specific data (para. 0170 describes designing the implant to be made to order for an individual patient, where the fit is based upon patient information; Fig. 1A-1C show a procedure for obtaining patient data) to minimize the amount of bone resected in one or more corresponding predetermined resection cuts (para. 0089 describes designing the implant to abut the bone so that no bone needed to be removed except for the bone removed to hold the device in place, which preserves bone stock; para. 0028-0029 regarding providing methods of repairing joints with only minimal or, in some instances, no loss in bone stock; para. 0196); [claim 3] wherein the one or more patient-engineered bone cuts (para. 0096 & Fig. 4A show an additional embodiment that describes the bone cuts, which can be performed on the implant 300) substantially negatively-match one or more predetermined resection cuts (para. 0101 describes how the surface 404 matches the shape of the bone, where matching means that the two components fit together, essentially the same as negative-matching; para. 0072 describes how the upper surface 202 of the compatible implant 200 can be negatively matched with an opposing joint surface; para. 0074 describes how the lower surface 204 of the compatible implant 200 that matches the surface of the bone); [claim 5] wherein the pre-primary articular implant component (300) is selected from the group consisting of a knee joint implant component, a hip joint implant component, a shoulder joint implant component, and a spinal implant component (para. 0094 describes the implant 300 being for a knee joint 1020; Fig. 3H); [claim 6] wherein the pre-primary articular implant component (300) is a knee joint implant component (para. 0094 describes the implant 300 being for a knee joint 1020; Fig. 3H); [claim 7] wherein the pre-primary articular implant component (300) is a femoral implant component (para. 0088 describes using the implant on the surface of the femur 1024; Fig. 3H shows the implant 300 on a condyle of the femur 1024; para. 0017, 0094); and, [claim 9] an implant component thickness in one or more regions that is selected and/or designed from patient-specific data (para. 0028 describes designing the shape of the implant, including its thickness, based upon images of the patient in the area to be implanted; para. 0033 describes taking measurement of the patient that will affect the implant design, including its thickness; para. 0170 describes obtaining patient data; Fig. 1C, step 130 or 132) to minimize the amount of bone resected (para. 0028 describes where the methods to design the implant will result in minimal or no loss of bone stock; para. 0029, 0196).

Regarding claim 10, Burdulis discloses the pre-primary articular implant component of claim 9, and Burdulis further discloses wherein the one or more regions comprises the implant component thickness (Fig. 2C-2E show different thickness of a compatible implant about different regions; para. 0077) perpendicular to a planar bone cut (such as distal cut 496 in Fig. 4A, where the thickness, in the same vein as that shown in Fig. 2C-2E, is perpendicular to the cut 496) and between the planar bone cut and the joint-surface of the implant component (surface 202 faces the joint in the embodiment of Fig. 2C-2E; Fig. 3J & 4A show further embodiments with a thickness between the bone cut and the joint facing surface at the bottom; para. 0028 describes designing the implant to have a certain thickness to minimize bone loss).

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of:

Regarding claim 11, Burdulis discloses a method for minimizing resected bone from a single patient in need of an articular implant replacement procedure (Title and Abstract), the method comprising: (a) identifying unwanted tissue from one or more images of the patient's joint (para. 0068-0070 describes creating a model of the patient's joint in order to determine the location of diseased tissue; para. 0014, 0032-0038; Fig. 1A-1C, steps 10, 30 or steps 100, 110, 120); (b) identifying a combination of resection cuts (para. 0068 regarding the size of the defect to be repaired can be determined; para. 0196 describes cuts to resect bone can be provided, if necessary; para. 0040) and implant component features (para. 0036 describes implant features) that remove the unwanted tissue (Fig. 1C, step 140 & para. 0039 describes removing cartilage or bone after the proceeding steps of Fig. 1A-1C have determined the appropriate tissue to remove) and also provide maximum bone preservation (para. 0068 regarding an appropriate therapy (e.g., articular repair system) can be selected such that as much as possible of the healthy, surrounding tissue is preserved; Fig. 1A-1B, step 40 described in para. 0034 describes creating an image of the diseased joint that projects the joint in a corrected condition); and (c) selecting and/or designing for the patient (Fig. 1C, step 132 describes generating a patient specific implant; para. 0039) a combination of resection cuts (para. 0068 regarding the size of the defect to be repaired can be determined; para. 0196 describes cuts to resect bone can be provided, if necessary) and implant component features (para. 0036 describes designing the implant features) that provide removal of the unwanted tissue (Fig. 1C, step 140 & para. 0039 describes removing cartilage or bone after the proceeding steps of Fig. 1A-1C have determined the appropriate tissue to remove) and maximum bone preservation (para. 0068 regarding an appropriate therapy (e.g., articular repair system) can be selected such that as much as possible of the healthy, surrounding tissue is preserved; Fig. 1A-1C, steps 50, 52 or steps 130, 132 describe selecting or designing an implant for the patient; para. 0032-0040).

Regarding claim 12, Burdulis discloses a method for making an articular implant component for a single patient in need of an articular implant replacement procedure (Title and Abstract), the method comprising: (a) identifying unwanted tissue from one or more images of the patient's joint (para. 0068-0070 describes creating a model of the patient's joint in order to determine the location of diseased tissue; para. 0014, 0032-0038; Fig. 1A-1C, steps 10, 30 or steps 100, 110, 120); (b) identifying a combination of resection cuts (para. 0068 regarding the size of the defect to be repaired can be determined; para. 0196 describes cuts to resect bone can be provided, if necessary) and implant component features (para. 0036 describes implant features) that remove the unwanted tissue (Fig. 1C, step 140 & para. 0039 describes removing cartilage or bone after the proceeding steps of Fig. 1A-1C have determined the appropriate tissue to remove) and also provide maximum bone preservation (para. 0068 regarding an appropriate therapy (e.g., articular repair system) can be selected such that as much as possible of the healthy, surrounding tissue is preserved; Fig. 1A-1B, step 40 described in para. 0034 describes creating an image of the diseased joint that projects the joint in a corrected condition); and (c) selecting and/or designing (Fig. 1A-1C, steps 50, 52 or steps 130, 132) a combination of resection cuts (para. 0068 regarding the size of the defect to be repaired can be determined; para. 0196 describes cuts to resect bone can be provided, if necessary; para. 0040) and implant component features (para. 0036 describes designing the implant features) that provide removal of the unwanted tissue (Fig. 1C, step 140 & para. 0039 describes removing cartilage or bone after the proceeding steps of Fig. 1A-1C have determined the appropriate tissue to remove) and maximum bone preservation (para. 0068 regarding an appropriate therapy (e.g., articular repair system) can be selected such that as much as possible of the healthy, surrounding tissue is preserved; Fig. 1A-1C, steps 50, 52 or steps 130, 132 describe selecting or designing an implant for the patient; para. 0032-0040).

Regarding claims 13 and 14, Burdulis discloses the method of claim 11, and further discloses [claim 13] wherein the unwanted tissue is diseased tissue or deformed tissue (para. 0014 describes replacing a diseased area of tissue; para. 0038 describes determining the size of diseased tissue to help create the implant); and [claim 14] wherein step (c) comprises designing for the single patient (Fig. 1C, step 132 describes generating a patient specific implant) a combination of resection cuts (para. 0068 regarding the size of the defect to be repaired can be determined; para. 0196 describes cuts to resect bone can be provided, if necessary; para. 0040) and implant component features (para. 0036 describes designing the implant features) that provide removal of the unwanted tissue (Fig. 1C, step 140 & para. 0039 describes removing cartilage or bone after the proceeding steps of Fig. 1A-1C have determined the appropriate tissue to remove) and maximum bone preservation (para. 0068 regarding an appropriate therapy (e.g., articular repair system) can be selected such that as much as possible of the healthy, surrounding tissue is preserved; Fig. 1A-1C, steps 50, 52 or steps 130, 132 describe selecting or designing an implant for the patient; para. 0032-0040).

Regarding claim 15, Burdulis discloses the method of claim 14, and Burdulis further discloses wherein designing comprises manufacturing (para. 0105 describes manufacturing the implant; para. 0160-0180 describes the components of manufacturing the implant, such as shaping, sizing and rapid prototyping).

Regarding claim 17, Burdulis discloses the method of claim 11, and Burdulis further discloses wherein a bone preservation measurement (para. 0069, 0089 describe preserving healthy tissue, including bone and cartilage) is selected from the group consisting of total volume of bone resected, volume of bone resected from one or more resection cuts, volume of bone resected to fit one or more implant component bone cuts, average thickness of bone resected, average thickness of bone resected from one or more resection cuts, average thickness of bone resected to fit one or more implant component bone cuts, maximum thickness of bone resected, maximum thickness of bone resected from one or more resection cuts, maximum thickness of bone resected to fit one or more implant component bone cuts (para. 0077 describes the implant thickness is a function of the bone and/or cartilage to be replaced along its length or width; based upon this measurement, one can determine a volume or thickness of bone resected in order to create an implant that matches the surface as described in para. 0028, 0068-0070).

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Regarding claims 18-21, Burdulis discloses the method of claim 11, and Burdulis further discloses [claim 18] wherein step (a) also includes identifying a minimum implant component thickness for the single patient (para. 0077 describes determining the thickness of the implant, which is a function of the thickness of bone and/or cartilage to be replaced; para. 0043, 0074 describe matching the implant with the surrounding tissue; the thickness will inherently have a minimum and maximum range in order to match the surrounding tissue; para. 0033, 0069 describe how measurements are made for a single patient); [claim 19] wherein step (b) also includes identifying a combination of resection cuts (para. 0068 regarding the size of the defect to be repaired can be determined; para. 0196 describes cuts to resect bone can be provided, if necessary) and/or implant component features (para. 0036 describes implant features) that provide a minimum implant thickness determined for the single patient (para. 0077 describes determining the profile features and thickness of the implant, which is a function of the thickness of bone and/or cartilage to be replaced; para. 0043, 0074 describe matching the implant with the surrounding tissue; the thickness will inherently have a minimum and maximum range in order to match the surrounding tissue; para. 0033, 0069 describe how measurements are made for a single patient); [claim 20] wherein step (c) includes selecting and/or designing (Fig. 1A-1C, steps 50, 52 or steps 130, 132) the combination of resection cuts (para. 0068 regarding the size of the defect to be repaired can be determined; para. 0196 describes cuts to resect bone can be provided, if necessary; para. 0040) and/or implant component features (para. 0036 describes designing the implant features) that provides at least a minimum implant thickness for the single patient (para. 0077 describes determining the profile features and thickness of the implant, which is a function of the thickness of bone and/or cartilage to be replaced; para. 0043, 0074 describe matching the implant with the surrounding tissue; the thickness will inherently have a minimum and maximum range in order to match the surrounding tissue; para. 0033, 0069 describe how measurements are made for a single patient); and, [claim 21] wherein the minimum implant component thickness (para. 0138 describes having the implant thickness similar to the tissue being replaced) is based on one or more of femur and/or condyle size or patient weight (para. 0077 regarding The actual thickness at a particular location of the implant 200 is a function of the thickness of the cartilage and/or bone to be replaced; para. 0152 describes designing the implant to replace the weight bearing portion of a femoral condyle; para. 0068, 0147).

Regarding claim 22, Burdulis discloses the method of claim 11, and Burdulis further discloses wherein the articular implant component (300) is a femoral implant component (para. 0088 describes using the implant on the surface of the femur 1024; Fig. 3H shows the implant 300 on a condyle of the femur 1024; para. 0017, 0094).

Claims 36 and 38-40 lack novelty under PCT Article 33(2) as being anticipated by Richardson.

Regarding claim 36, Richardson a femoral implant component (Title and Abstract) comprising: (a) a joint-facing surface (external articular surface 18; para. 0065; Fig. 2) comprising lateral (lateral articular surface 24 and lateral posterior condyle articular surface 28) and medial condylar surface portions (medial articular surface 26 and medial posterior condyle articular surface 30; Fig. 2 & 6; para. 0068-0071), and (b) a bone-facing surface (non-articular internal surface 20; para. 0065; Fig. 2) comprising an anterior bone cut (anterior non-articular surface 36; Fig. 5; para. 0073 describes chamfer surfaces on the interior; para. 0076), wherein the distance between the anterior bone cut (36) and the lateral condylar surface portion (28) is different from the distance between the anterior bone cut (36) and the medial condylar surface portion (30; Fig. 5 & 5A show the different radii of curvature R1, R2 that create a different distance from the anterior surface 36 to the respective lateral surface 28 or medial surface 30; para. 0083, 0089).

Regarding claim 38, Richardson discloses a femoral implant component (Title and Abstract) comprising: (a) lateral (lateral articular surface 24 and lateral posterior condyle articular surface 28) and medial condylar portions (medial articular surface 26 and medial posterior condyle articular surface 30; Fig. 2 & 6; para. 0068-0071), and (b) a bone-facing surface (internal surface 20; Fig. 2; para. 0073) comprising a distal bone cut facet (distal non-articular surfaces 40a, 40b; para. 0081; Fig. 5 & 5b) that is asymmetric about its center line (para. 0057 describes the sagittal plane) in a sagittal plane (para. 0089 describes the different radius of curvatures about the sagittal plane in Fig. 5A, making the facets 40a, 40b asymmetric in that plane; Fig. 8 shows the asymmetric facets 40a, 40b).

Regarding claim 39 and 40, Richardson discloses the femoral implant component of claim 38, and further discloses [claim 39] wherein the asymmetric distal bone cut facet (surface 40a) lies on the bone-facing surface of the lateral condyle (Fig. 5 shows the surface 40a on the portion of the device with a radius R1 described in para. 0083; Fig. 6 shows R1 is associated with the lateral surface 24 that forms the lateral condyle articular surface as described in para. 0083; para. 0089 describes the different radius of curvatures about the sagittal plane in Fig. 5A, making the facets 40a, 40b asymmetric to one another); and, [claim 40] wherein the asymmetric distal bone cut facet (surface 40b) lies on the bone-facing surface of the medial condyle (Fig. 5 shows the surface 40b on the portion of the device with a radius R2 described in para. 0083; Fig. 6 shows R2 is associated with the medial surface 26 that forms the medial condyle articular surface as described in para. 0083; para. 0089 describes the different radius of curvatures about the sagittal plane in Fig. 5A, making the facets 40a, 40b asymmetric to one another).

Claims 4, 8, and 23 lack an inventive step under PCT Article 33(3) as being obvious over Burdulis et al. (hereinafter Burdulis).

Regarding claim 4, Burdulis discloses the pre-primary articular implant component of claim 3, and Burdulis further discloses wherein the predetermined resection cuts are at a first depth (para. 0074 describes articular resurfacing that produce the resection cuts). Burdulis fails to explicitly disclose a first depth that allows, in a subsequent procedure, removal of additional bone to a second depth required for a traditional primary implant component. However, Burdulis describes making only a few resection cuts (para. 0014), removing only minimal amounts of bone stock (para. 0028), and preserving as much as the healthy tissue as possible after resection of diseased tissue (para. 0068). Additionally Burdulis describes a traditional implant, which requires resecting significant amounts of bone and/or cartilage tissue (para. 0006-0008). It would have been obvious to one of ordinary skill in the art at the time the invention was made to repeat the step of resecting bone, only at a second depth to allow for a traditional implant, since a mere duplication of essential working parts of a device involves only routine skill in the art. Furthermore, because only a minimal amount of bone is removed with the first resection, there should be enough additional bone to perform a second resection to the depth required of a traditional implant.

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Regarding claim 8, Burdulis discloses the pre-primary articular implant component of claim 1, and Burdulis further discloses patient-engineered bone cuts (para. 0089 describes designing the surface of the implant to abut the bone, where para. 0095 & Fig. 3J-3K show examples of the cuts made to match the implant with the portion of the patient's bone where the device will be used; para. 0096 & Fig. 4A show an additional embodiment where a series of cuts are made on the device; para. 0170 describes designing the implant to be made to order for an individual patient, where the fit is based upon patient information). Burdulis fails to explicitly disclose six or more bone cuts. However, Burdulis describes using five cuts on the implant (Fig. 4A), which are a posterior cut (498), anterior cut (497), distal cut (496), and two chamfer cuts (495; Fig. 4A; para. 0096), in order to mate specifically with the corresponding portion of the patient's bone or cartilage (para. 0070, 0095). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use six or more bone cuts, rather than five bone cuts, since discovering the optimum value of a result effective variable involves only routine skill in the art, where the purpose it to provide an implant surface that closely matches the surface of the bone or cartilage where the implant will be placed.

Regarding claim 23, Burdulis discloses a femoral implant component comprising: (a) a joint-facing surface (curved mating surface 302) comprising a bearing surface portion (para. 0127 describes a weight bearing surface of Fig. 3-8, such as the outer surface shown in Fig. 3H-3I; para. 0152-0155 describes using the implant to replace an articular weight bearing surface), and (b) a bone-facing surface (named convex joint abutting surface or bone mating surface 304; para. 0089-0091 describes how surface 304 faces the bone, shown in Fig. 3G, and held in place via anchors 306; para. 0091) comprising bone cuts (para. 0089 describes designing the surface of the implant to abut the bone, where para. 0095 & Fig. 3J-3K show examples of the cuts made to match the implant with the portion of the patient's bone where the device will be used; para. 0096 & Fig. 4A show an additional embodiment where a series of cuts are made on the device). Burdulis fails to explicitly disclose six or more bone cuts. However, Burdulis describes using five cuts on the implant (Fig. 4A), which are a posterior cut (498), anterior cut (497), distal cut (496), and two chamfer cuts (495; Fig. 4A; para. 0096), in order to mate specifically with the corresponding portion of the patient's bone or cartilage (para. 0070, 0095). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use six or more bone cuts, rather than five bone cuts, since discovering the optimum value of a result effective variable involves only routine skill in the art, where the purpose it to provide an implant surface that closely matches the surface of the bone or cartilage where the implant will be placed.

Claim 37 lacks an inventive step under PCT Article 33(3) as being obvious over Richardson.

Regarding claim 37, Richardson discloses the femoral implant component of claim 36, and further discloses wherein the two or more facets or portions (posteriors surfaces 44a, 44b form the planar portion of the lateral and medial surfaces 24, 26 shown in Figs. 5 & 5A; para. 0082) are non-parallel (Figs. 5 & 5A show the surfaces 44a and 44b as slightly non-parallel to one another; this is due to the varying radius of curvature R1, R2 for each surface this changes the angle for the surfaces in order to locate the components in the proper position on the knee as described in para. 0083, 0089). Richardson fails to explicitly disclose wherein the two facets are substantially non-parallel. It would have been obvious to one of ordinary skill in the art at the time the invention was made to the two facets substantially non-parallel, since a mere change in shape of an element involves only routine skill in the art, the purpose being to make the angles of the facets the most appropriate to ensure proper positioning.

Claims 24-35 lack an inventive step under PCT Article 33(3) as being obvious over Burdulis et al. (hereinafter Burdulis) in view of Richardson.

Regarding claim 24, Burdulis discloses a femoral implant component comprising: (a) a joint-facing surface (curved mating surface 302) comprising a bearing surface portion (para. 0127 describes a weight bearing surface of Fig. 3-8, such as the outer surface shown in Fig. 3H-3I; para. 0152-0155 describes using the implant to replace an articular weight bearing surface), and (b) a bone-facing surface (named convex joint abutting surface or bone mating surface 304; para. 0089-0091 describes how surface 304 faces the bone, shown in Fig. 3G, and held in place via anchors 306; para. 0091) comprising a distal bone cut (distal cut 496; Fig. 4A; para. 0096) having two or more planar facets or portions (Fig. 4A & 4B show two planar facets 410, 420; para. 0096, 0100). Burdulis fails to explicitly disclose comprising the two or more planar facets or portions that are non-coplanar with each other. Richardson teaches of a prosthetic knee, comprising two or more planar facets or portions (Fig. 2 & 6 show the two sections that form facets; para. 0068, 0069; para. 0082 describes the posteriors surfaces 44a, 44b, part of the interior surfaces 20 of the lateral and medial surfaces 24, 26 that form the facets shown in Fig. 5, as generally flat) that are non-coplanar with each other (Fig. 2 & 5 show the internal surfaces 44a, 44b of the lateral posterior condyle articular surface 28 and medial posterior condyle articular surface 30, respectively, as non-coplanar with each other; para. 0070-0080). It would have been obvious to one of skill in the art at the time of invention to modify the invention of Burdulis to include non-coplanar facets as taught by Richardson as this allows the facets to be better positioned relative to the corresponding mating bone portion, in order to reduce the amount of bone removed to install the implant.

Regarding claim 25, Burdulis as modified discloses the femoral implant component of claim 24, but Burdulis fails to explicitly disclose wherein the two or more facets or portions are non-parallel with each other. Richardson teaches of a prosthetic knee, wherein the two or more facets or portions (posteriors surfaces 44a, 44b form the planar portion of the lateral and medial surfaces 24, 26 shown in Fig. 5 & 5A; para. 0082) are non-parallel with each other (Fig. 5 & 5A show the surfaces 44a and 44b as slightly non-parallel to one another; this is due to the varying radius of curvature R1, R2 for each surface this changes the angle for the surfaces in order to locate the components in the proper position on the knee as described in para. 0083, 0089). It would have been obvious to one of skill in the art at the time of invention to modify the invention of Burdulis as modified to include non-parallel facets as taught by Richardson as this allows the facets to be better positioned relative to the corresponding mating bone portion, in order to reduce the amount of bone removed to install the implant.

Regarding claim 26, Burdulis as modified discloses the femoral implant component of claim 24, and Burdulis further discloses wherein a first of the two or more facets or portions is on a lateral condyle bone-facing surface (lateral condyle component 410; Fig. 4B; para. 0100; Fig. 4G shows the implant surface on the lateral condyle 1002, described in para. 0102) and the second is on a medial condyle bone-facing surface (medial condyle component 420; Fig. 4B; para. 0100; Fig. 4G shows the implant surface on the medial condyle 1004, described in para. 0102).

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Regarding claim 27, Burdulis discloses a femoral implant component comprising: (a) a joint-facing surface (curved mating surface 302) comprising a bearing surface portion (para. 0127 describes a weight bearing surface of Fig. 3-8, such as the outer surface shown in Fig. 3H-3I; para. 0152-0155 describes using the implant to replace an articular weight bearing surface), and (b) a bone-facing surface (named convex joint abutting surface or bone mating surface 304; para. 0089-0091 describes how surface 304 faces the bone, shown in Fig. 3G, and held in place via anchors 306; para. 0091) comprising an anterior bone cut (anterior cut 497; Fig. 4A; para. 0096) having two or more planar facets or portions (Fig. 4A & 4B show two planar facets 410, 420; para. 0096, 0100). Burdulis fails to explicitly disclose comprising the two or more planar facets or portions that are non-coplanar with each other. Richardson teaches of a prosthetic knee, comprising two or more planar facets or portions (Fig. 2 & 6 show the two sections that form facets; para. 0068, 0069; para. 0082 describes the posteriors surfaces 44a, 44b, part of the interior surfaces 20 of the lateral and medial surfaces 24, 26 that form the facets shown in Fig. 5, as generally flat) that are non-coplanar with each other (Fig. 2 & 5 show the internal surfaces 44a, 44b of the lateral posterior condyle articular surface 28 and medial posterior condyle articular surface 30, respectively, as non-coplanar with each other; para. 0070-0080). It would have been obvious to one of skill in the art at the time of invention to modify the invention of Burdulis to include non-coplanar facets as taught by Richardson as this allows the facets to be better positioned relative to the corresponding mating bone portion, in order to reduce the amount of bone removed to install the implant.

Regarding claim 28, Burdulis as modified discloses the femoral implant component of claim 27, but Burdulis fails to explicitly disclose wherein the two or more planar facets or portions are non-parallel with each other. Richardson teaches of a prosthetic knee, wherein the two or more planar facets or portions (posteriors surfaces 44a, 44b form the planar portion of the lateral and medial surfaces 24, 26 shown in Fig. 5 & 5A; para. 0082) are non-parallel with each other (Fig. 5 & 5A show the surfaces 44a and 44b as slightly non-parallel to one another; this is due to the varying radius of curvature R1, R2 for each surface this changes the angle for the surfaces in order to locate the components in the proper position on the knee as described in para. 0083, 0089). It would have been obvious to one of skill in the art at the time of invention to modify the invention of Burdulis as modified to include non-parallel facets as taught by Richardson as this allows the facets to be better positioned relative to the corresponding mating bone portion, in order to reduce the amount of bone removed to install the implant.

Regarding claim 29, Burdulis discloses a femoral implant component comprising: (a) a joint-facing surface (curved mating surface 302) comprising a bearing surface portion (para. 0127 describes a weight bearing surface of Fig. 3-8, such as the outer surface shown in Fig. 3H-3I; para. 0152-0155 describes using the implant to replace an articular weight bearing surface), and (b) a bone-facing surface (named convex joint abutting surface or bone mating surface 304; para. 0089-0091 describes how surface 304 faces the bone, shown in Fig. 3G, and held in place via anchors 306; para. 0091) comprising a posterior bone cut (posterior cut 498; Fig. 4A; para. 0096) having two or more planar facets or portions (Fig. 4A & 4B show two planar facets 410, 420; para. 0096, 0100). Burdulis fails to explicitly disclose comprising the two or more planar facets or portions that are non-parallel with each other. Richardson teaches of a prosthetic knee, comprising two or more planar facets or portions (Fig. 2 & 6 show the two sections that form facets; para. 0068, 0069; para. 0082 describes the posteriors surfaces 44a, 44b, part of the interior surfaces 20 of the lateral and medial surfaces 24, 26 that form the facets shown in Fig. 5, as generally flat) that are non-parallel with each other (Fig. 5 & 5A show the surfaces 44a and 44b as slightly non-parallel to one another; this is due to the varying radius of curvature R1, R2 for each surface this changes the angle for the surfaces in order to locate the components in the proper position on the knee as described in para. 0083, 0089). It would have been obvious to one of skill in the art at the time of invention to modify the invention of Burdulis to include non-parallel facets as taught by Richardson as this allows the facets to be better positioned relative to the corresponding mating bone portion, in order to reduce the amount of bone removed to install the implant.

Regarding claim 30, see claim 26.

Regarding claim 31, Burdulis discloses a femoral implant component comprising: (a) a joint-facing surface (curved mating surface 302) comprising a bearing surface portion (para. 0127 describes a weight bearing surface of Fig. 3-8, such as the outer surface shown in Fig. 3H-3I; para. 0152-0155 describes using the implant to replace an articular weight bearing surface), and (b) a bone-facing surface (named convex joint abutting surface or bone mating surface 304; para. 0089-0091 describes how surface 304 faces the bone, shown in Fig. 3G, and held in place via anchors 306; para. 0091) comprising an anterior chamfer bone cut (second chamber cut 495 near the anterior portion, opposite the posterior cut 498 in Fig. 4A; para. 0096) having two or more planar facets or portions (Fig. 4A & 4B show two planar facets 410, 420; para. 0096, 0100). Burdulis fails to explicitly disclose comprising the two or more planar facets or portions that are non-coplanar with each other. Richardson teaches of a prosthetic knee, comprising two or more planar facets or portions (Fig. 2 & 6 show the two sections that form facets; para. 0068, 0069; para. 0082 describes the posteriors surfaces 44a, 44b, part of the interior surfaces 20 of the lateral and medial surfaces 24, 26 that form the facets shown in Fig. 5, as generally flat) that are non-coplanar with each other (Fig. 2 & 5 show the internal surfaces 44a, 44b of the lateral posterior condyle articular surface 28 and medial posterior condyle articular surface 30, respectively, as non-coplanar with each other; para. 0070-0080). It would have been obvious to one of skill in the art at the time of invention to modify the invention of Burdulis to include non-coplanar facets as taught by Richardson as this allows the facets to be better positioned relative to the corresponding mating bone portion, in order to reduce the amount of bone removed to install the implant.

Regarding claim 32, see claim 28.

Regarding claim 33, see claim 26.

Regarding claim 34, Burdulis discloses a femoral implant component comprising: (a) a joint-facing surface (curved mating surface 302) comprising a bearing surface portion (para. 0127 describes a weight bearing surface of Fig. 3-8, such as the outer surface shown in Fig. 3H-3I; para. 0152-0155 describes using the implant to replace an articular weight bearing surface), and (b) a bone-facing surface (named convex joint abutting surface or bone mating surface 304; para. 0089-0091 describes how surface 304 faces the bone, shown in Fig. 3G, and held in place via anchors 306; para. 0091) comprising a posterior chamfer bone cut (first chamber cut 495 near the posterior cut 498 in Fig. 4A; para. 0096) having two or more planar facets or portions (Fig. 4A & 4B show two planar facets 410, 420; para. 0096, 0100). Burdulis fails to explicitly disclose comprising the two or more planar facets or portions that are non-parallel with each other. Richardson teaches of a prosthetic knee, comprising two or more planar facets or portions (Fig. 2 & 6 show the two sections that form facets; para. 0068, 0069; para. 0082 describes the posteriors surfaces 44a, 44b, part of the interior surfaces 20 of the lateral and medial surfaces 24, 26 that form the facets shown in Fig. 5, as generally flat) that are non-parallel with each other (Fig. 5 & 5A show the surfaces 44a and 44b as slightly non-parallel to one another; this is due to the varying radius of curvature R1, R2 for each surface this changes the angle for the surfaces in order to locate the components in the proper position on the knee as described in para. 0083, 0089). It would have been obvious to one of skill in the art at the time of invention to modify the invention of Burdulis to include non-parallel facets as taught by Richardson as this allows the facets to be better positioned relative to the corresponding mating bone portion, in order to reduce the amount of bone removed to install the implant.

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Regarding claim 35, see claim 26.

Claims 41-43 lack an inventive step under PCT Article 33(3) as being obvious over Richardson in view of Ek et al. (hereinafter Ek).

Regarding claim 41, Richardson discloses a femoral implant component (Title and Abstract) having a bone-facing surface (non-articular internal surface 20; para. 0065; Fig. 2) comprising one or more bone cuts (para. 0073 regarding The bone contacting non-articular internal surface 20 includes a plurality of chamfer surfaces; 36, 38, 40, 42, 44 are all bone cut surfaces in Fig. 5), wherein at least one of the one or more bone cuts (44a, 44b) comprises two planar bone cut facets (surfaces 44a and 44b forms planar facets as show in Fig. 5 & 5A; para. 0081 describes the generally flat surface) separated by at least one cut (38; para. 0081 regarding The anterior non-articular surface 36 and the two distal nonarticular surfaces 40a,40b are coupled together by the distal anterior non-articular surface 38; Fig. 5 shows how surface 44a, 42a, and 40a together form one end of the implant, while 44b, 42b, and 40b form the second end; surface 38 connects the two ends together). Richardson fails to explicitly disclose surfaces separated by a step cut. Ek teaches of a system for joint resurface repair, comprising surfaces separated (parts of top surface 42) by a step cut (stepped machine cuts 43; Fig. 4A-4C shows the step cut 43 separating surfaces of the top surface 42; pg. 19, lns. 10-18 describes the stepped cuts 43). It would have been obvious to one of skill in the art at the time of invention to modify the invention of Richardson to include surfaces separated by a step cuts as taught by Ek as this type of cut allows two separate surfaces to connect together in a manner will best fit the contour of the bone the surface will be placed on.

Regarding claims 42 and 43, Richardson as modified discloses the femoral implant component of claim 41, but Richardson fails to explicitly disclose [claim 42] wherein the step cut is substantially perpendicular to at least one of the bone cut facets; and, [claim 43] wherein the step cut rises or falls at about 30 degrees or more from at least one of the bone cut facet planes. Ek teaches of a system for joint resurface repair, [claim 42] wherein the step cut (43) is substantially perpendicular to at least one of bone cut facets (part of top surface 42; pg. 19, lns. 10-18 describes using square cross section cuts, which are perpendicular to the surfaces created by the stepped cuts 43 on surface 42; Fig. 4A-4C); and, [claim 43] wherein the step cut (43) rises or falls at about 30 degrees or more from at least one of bone cut facet planes (part of top surface 42; pg. 19, lns. 10-18 describes using square cross section cuts, which are perpendicular to the surfaces created by the stepped cuts 43 on surface 42; the perpendicular cut is 90°; Fig. 4A-4C). It would have been obvious to one of skill in the art at the time of invention to modify the invention of Richardson as modified to include a step cut that separates facet planes by more than 30 degrees, or is substantially perpendicular as taught by Ek as this type of cut allows two separate surfaces to connect together in a manner will best fit the contour of the bone the surface will be placed on.

Claims 1-15 and 17-43 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.